

**REMARKS**

Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration of the subject application based on the foregoing amendments and the following remarks.

Claims 1 and 73-120 are pending in the subject application. Claims 108, 111, 116-118 and 120 are acknowledged by the Examiner as being allowable. Claim 1 is canceled.

Claims 1, 73, 78-83, and 94-100 stand rejected under 35 U.S.C. §102 and/or 35 U.S.C. §112, second paragraph. The Examiner objected to claims 78, 80-82, 84, 88, 90-92, 95, 97-102, 106, 109, 110, 112-115 and 119 for identified informalities and also indicated that the claims 84-93, 101, 107, 109-110, 112-115 and 119 would be allowable if appropriately re-written or amended to overcome the objections. In addition, claims 74-77 were objected to as depending from a rejected base claim, however, the Examiner indicated that these claims would be allowable if appropriately re-written in independent form.

Claim 1 was canceled in the instant amendment without prejudice. Claims 78, 80-82, 84, 88, 90-92, 95, 97-100, 102, 106, 109, 110, 112-115 and 119 were amended as suggested by the Examiner to overcome the objection and claim 101 was amended to address the Examiner's objection.

Claims 76, 94 and 100 were amended to address the Examiner's non-art based rejections.

Claim 74 was re-written in independent form as suggested by the Examiner. In addition, each of claims 75-79 81, and 83 were amended to depend from claim 74.

Claims 73, 94 and 100 were amended for clarity so as to more clearly claim the present invention.

Claims 73-74, 78, 81, 84, 88, 91, 94-95, 98, 100-102, 105, 108, 110 and 113 were amended so the portion of the fixation member or the like is described as being made up of a flexible material or being a flexible portion now reads as a compressible material or portion. See for example, page 25 and the discussion for Figs. 17A-C for support for the amendment.

Claims 103-153 were added to more distinctly claim embodiments/ aspects of the present invention.

The foregoing amendments to the claims are supported by the originally filed disclosure.

The specification also was objected to because of an identified informality and correction required. The specification was amended to address the Examiner's objections and/or rejections. The amendment(s) to the specification do not introduce new matter because they either are editorial in nature or are supported by the originally filed disclosure.

#### 35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS

Claims 76, 94 and 100 stand rejected under 35 U.S.C. §112 on the grounds that there are antecedent basis, indefiniteness and/or vagueness concerns with the identified claims.

As provided above, claims 76, 94 and 100 were amended in the foregoing amendment to address the non-art concerns specifically identified by the Examiner. Applicants thus believe that the areas of rejection have been identified and addressed in the foregoing amendment. Thus, it is respectfully submitted that these claims satisfy the requirements of 35 U.S.C. §112 and, as such, are in a condition for allowance.

#### 35 U.S.C. §102 REJECTIONS

The Examiner rejected claims 1, 73, 78-83 and 94-100 under 35 U.S.C. §102(b) as being anticipated by Steffee [USP 4,709,303]. Applicants respectfully traverse as discussed below.

Because claims 73, 94 and 100 were amended in the instant amendment, the following discussion refers to the language of these amended claims. However, only those amended features specifically relied upon to distinguish the claimed invention from the cited prior art shall be considered as being made to overcome the cited reference. The following addresses the within rejection as to the following grouping of claims.

## **CLAIM 1**

Because claim 1 was canceled in the foregoing amendment, Applicants do not believe that this claim need be addressed further herein.

## **CLAIMS 78-83**

As indicated above, each of claims 78, 79 and 81-83 were amended so that each depends directly from claim 74. As a result of the foregoing amendment, claim 80 also depends indirectly from claim 74. As indicated herein claim 74 was amended so as to place this claim in allowable form. As such, each of claim 78-83 are considered to be in allowable form at least because of their dependency from an allowable claim.

## **CLAIMS 73, 94-100**

Claim 73 was amended for clarity so as to more clearly claim the intravertebral prosthetic device securing method of the present invention. The above-referenced Office Action asserts that Steffe discloses a method for securing an intravertebral prosthetic device [24] as set forth in claim 1. Applicants respectfully disagree with the characterization of what is being disclosed in Steffe as it applies to the present invention.

The elements in Steffe corresponding to reference numerals 50, 52 and 70 are respectively the fasteners 50, 52 and a wire cable 70, whose ends are secured together by a suitable connector. As disclosed in Steffe (e.g., see Figure 4 and col. 3, lines 20-56) each of the fasteners 50, 52 is inserted between the fibrocartilaginous disk 60b and the surface 22a of the bone portion 22. One fastener 50 is driven through the surface 22a, through the bone portion 22, through the entire thickness of the bone graft 24 and into the other bone portion 26. The other fastener 52 is similarly driven in an opposite direction entirely through one portion 26, through the entire bone graft and

into the other bone portion 50. It is further indicated in Steffe that after driving these fasteners 50, 52 into the bone portions 22, 26 and the bone graft, a wire cable is placed through openings 71 in the driving ends of the respective fastener.

In contrast to the present invention, in Steffe the wire cable does not pass through the bone graft, (i.e., the prosthetic device). Rather Steffe discloses and teaches having the wire cable 70 arranged so that it passes through openings 71 in the driving ends portions of each of the fasteners 50, 52. Consequently, the structure and arrangement disclosed and taught in Steffe has the wire cable passing between the fasteners external to or outside of the bone graft 24 such as that shown in Fig. 5 of Steffe.

Further, in the methodology disclosed in Steffe each fastener 50, 52 is driven through one of the bone portions, through the bone graft and into the other bone portion. However, and as more particularly illustrated in Figs. 5 and 6 of Steffe, the driving ends of each fastener must necessarily extend above or beyond the surface of bone portion. This is particularly necessary so the wire cable can be attached after the driving is completed, as is disclosed and taught in Steffe. Consequently, this yields a structure or arrangement that extends beyond the confines or boundaries of the bony structure of the spine.

In contrast to Steffe, the methodology of the present invention allows an intravertebral device to be secured between two adjacent vertebrae by implanting an arcuate fixation member between the adjacent vertebrae and passing a portion of the fixation member through the prosthetic device. The methodology of the present invention further provides that each end of the fixation member is secured to one of the vertebrae. Following such a methodology yields an arrangement or structure in which the implanted fixation member can be essentially submerged within the adjacent vertebrae and the prosthetic device. Thus, the prosthetic device and the fixation member can be located so as to be within the general confines or boundaries of the bony structure of the spine. This is nowhere disclosed or taught in Steffe. Moreover, it is not possible for the methodology in Steffe to be modified so as to yield such an arrangement without necessarily destroying the

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intended purpose and operation of the apparatus disclosed in Steffee as well as departing from the intended method and flow of the method steps disclosed in Steffee.

Also, as described in Steffee the fasteners are driven completely through one bone portion and the bone graft and into the other bone portion. It thus is clear that the fasteners in Steffee are and must be of a solid or non-flexible construct, otherwise they could not be driven through the bone in the described fashion. Consequently, it cannot be said that Steffee inherently discloses having the fasteners include a flexible or compressible portion as is claimed by Applicants.

It is respectfully submitted that at least the foregoing remarks distinguishing the methodology of claim 73, also applies to distinguish the spinal intravertebral prosthetic system of claims 94-99 and the spinal intravertebral prosthetic system of claim 100.

In sum, the system, apparatus and methodology disclosed and taught in Steffee differs in numerous respects from the methodology and systems claimed by Applicants. Thus, it can hardly be said that Steffee discloses the methods and systems claimed by Applicants. Further, the systems, apparatuses and methods disclosed in Steffee cannot be modified so as to yield the methods, systems and devices of the present invention without destroying the intent purpose and function of the inventions disclosed in Steffee.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegel Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). It is clear from the foregoing remarks that the above identified claims are not anticipated by the cited reference/admitted prior art.

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It is respectfully submitted that for the foregoing reasons, claims 73, 78-83 and 94-100 are patentable over the cited reference and satisfy the requirements of 35 U.S.C. §102(b). As such, these claims, including the claims dependent therefrom are allowable.

CLAIMS 78, 80-82, 84, 88, 90-92, 95, 97-102, 106, 109, 110, 112-115 & 119

As indicated above, claims 78, 80-82, 84, 88, 90-92, 95, 97-102, 106, 109, 110, 112-115 and 119 were objected to because of the informalities identified on pages 2-3 of the above-referenced Office Action.

Applicants have amended claims 78, 80-82, 84, 88, 90-92, 95, 97-100, 102, 106, 109, 110, 112-115 and 119 as suggested by the Examiner.

As to claim 101, the identified concern for line 1 appeared to apply to claim 100 and not to claim 101. As such, Applicants further amended claim 100 to address this particular concern. Otherwise claim 101 was amended as suggested by the Examiner.

In view of the above-described amendments claims 78, 80-82, 84, 88, 90-92, 95, 97-102, 106, 109, 110, 112-115 and 119 are considered to be in acceptable form. As to claims 84-93, 101, 107, 109-110, 112-115 and 119, the Examiner had further indicated that these claims would be allowable if appropriately re-written or amended to overcome the objections. As such, these claims are thus considered to also be allowable in view of the foregoing amendments to the claims.

CLAIMS 74-77

In the above-referenced Office Action, claims 74-77 were objected to as being dependent upon a rejected base claim. It also was provided in the above-referenced Office Action, however, that these claims would be allowable if rewritten in independent form to include all the limitations of the base claim and any intervening claim(s).

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Claim 74 was re-written in the foregoing amendment so as to be in independent form and to include all the limitations of the base claim there being no intervening claim(s). As such, claim 74 is considered to be in allowable form.

As to claims 75-77, these claims were not re-written in independent form as suggested by the Examiner. These claims either depended from claim 74 or were amended so as to depend from claim 74. Applicants however, reserve the right to later amend the subject application so as to present any one or more of these claims in independent form or to add one or more independent claims that contain the limitations of any one or more of claims 75-77.

#### CLAIMS 103-153

As indicated above, claims 103-153 were added to more distinctly claim embodiments/aspects of the present invention. These claims are clearly supported by the originally filed disclosure, including the originally filed claims. It also is respectfully submitted that these added claims are patentable over the cited prior art on which the above-described rejection(s) are based.

#### SEPCIFICATION OBJECTION(S)

The Examiner objected to the specification of the subject application for the reasons provided on page 2 of the above-referenced Office Action. Applicants have amended the specification as suggested by the Examiner. It thus is respectfully submitted that for the foregoing reasons, the specification satisfies applicable Patent laws and rules and, therefore is considered acceptable.

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

Because the total number of claims and/or the total number of independent claims post amendment now exceed the highest number previously paid for, a check is enclosed herewith for

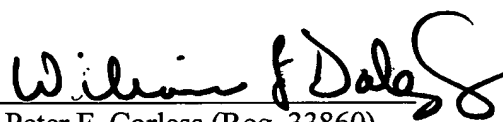
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the required additional fees. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner is hereby authorized and requested to charge Deposit Account No. **04-1105**.

Respectfully submitted,

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